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LETTERS TO THE EDITOR

Choice of Prosthetic Heart Valves: 20-Year Results of the Edinburgh Heart Valve Trial

A recent edition of the *Journal* carried a robust debate between David S. Bach (1) and Shahbudin H. Rahimtoola (2) on the choice of prosthetic heart valves for individual patients requiring valve replacement surgery. Bach's (1) thesis was that prosthetic heart valves have evolved over the years to provide superior hemodynamics and durability compared to older valves, which had been included in randomized trials. Rahimtoola's (2) commentary, "The next generation of prosthetic heart valves needs a proven track record of patient outcomes at ≥15 to 20 years," emphasized the importance of obtaining long-term data not available for the newer prostheses, and he stressed how important long-term data are from prospective randomized trials.

Bach (1) notes that in the Edinburgh Heart Valve Trial there was a trend favoring improved survival in association with the mechanical Bjork-Shiley prosthesis. We have recently published data from the 20-year follow-up of patients randomized in this trial. Interestingly, the trend toward improved survival at 12 years diminished as patients were followed for 20 years. Bach (1) also noted, "However, freedom from all valve-related complications for tissue and mechanical prostheses was indistinguishable at 12 years." In fact, when we followed our patients for survival without a major event (i.e., freedom from death, re-operation, major hemorrhage, embolism, or endocarditis) there was a significantly better survival in favor of the Bjork-Shiley prosthesis for those undergoing mitral valve replacement (3). This benefit became apparent after 10 to 12 years of follow-up and as survival cures continued to separate thereafter.

This difference in survival without a major event was almost entirely accounted for by the increased need for re-operation in patients who had received a bioprosthesis with increasing years of follow-up. There was no significant difference in survival without a major event in the subgroup of patients who had undergone aortic valve replacement. These results would not support Bach's (1) statement, namely that "Bioprostheses were superior to mechanical valves prior to 12 years after surgery and were equivalent thereafter." The risk of anticoagulant hemorrhage is of course not limited to those patients receiving a mechanical valve. We noted an increase in the use of anticoagulants in patients who had been randomized to receive a bioprosthesis during the course of the trial. At five years, 15% of patients with a porcine aortic prosthesis and 36% of those with a porcine mitral prosthesis were receiving warfarin; by 15 years this proportion had risen to 33% and 57%, respectively. The increasing use of warfarin with the passage of time reflected concomitant conditions such as atrial fibrillation and chamber dilation favoring the use of long-term anticoagulation.

These results emphasize the need for prolonged follow-up of patients in randomized trials of prosthetic heart valves as it is only with such prolonged follow-up that important differences between prostheses are seen to emerge. It is perhaps ironic that data from the Edinburgh Trial and the U.S. Department of Veterans Affairs trial have provoked such debate within the editorial pages of the *Journal of the American College of Cardiology*. We had submitted the manuscript of the 20-year follow-up to the *Journal* more than a year prior to Bach's (1) viewpoint and Rahimtoola's (2) commentary and previous editorial. The *Journal* declined our manuscript; acceptance may have cast more light than heat on the subsequent debate.

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REPLY

I am glad Dr. Bloomfield concurs with and re-emphasizes the importance of obtaining long-term (≥15 to 20 years) follow-up data in patients with prosthetic heart valves (PHVs). The 20-year results of the Edinburgh Heart Valve trial (1) (Edinburgh trial) are reviewed in the *Journal of the American College of Cardiology* series entitled "The Year in Cardiology" (2). This trial showed that at 20 years the incidence of re-operation in patients receiving the porcine PHV was very much higher than in patients receiving the mechanical PHV; after mitral valve replacement it was 77.6% versus 13.4% ± $p < 0.0001$ (1), and after aortic valve replacement it was 56.2% versus 7.4%, $p < 0.0001$. In the Veterans Affairs (3) and Edinburgh trials (1), major differences between the mechanical and bioprostheses that were statistically significant appeared after about 10 to 12 years of follow-up.

I agree that the Edinburgh and Veterans Affairs trials are very important and provide useful data, but they should not be used as the sole source on which to choose a PHV (3–5). In the Edinburgh trial (1), at 20 years the survival with original prosthesis intact was better with mechanical valve, but the total mortality was not significantly different between a mechanical and porcine PHV. Noncardiac causes accounted for 23% to 28% of the deaths; data (PHV vs. non-PHV) on the cardiac causes of death in those with mechanical and porcine PHVs are not provided. This information might help to understand why all-cause mortality was not significantly different. It is of interest that the 30-day mortality of re-operation was 14.2% (18.3% before 1987 and 9.4% after 1987) (1).

Finally, the review (4) had not dealt with stentless PHVs in any detail because long-term follow-up data was not available. The Commentary (5) was able to show that Dr. Bach's (6) unbridled